REPLY FILED UNDER EXPEDITED PROCEDURE PURSUANT TO 37 C.F.R. § 1.116

REMARKS

Reconsideration of the present application in view of the above amendments and following remarks is requested respectfully.

Claims 25 and 27 to 32 are pending. Claim 25 has been amended. No claims have been added or canceled.

It is submitted respectfully that the above amendments and attached Terminal Disclaimers (discussed in detail below) place the application in condition for allowance. Applicants believe that the claim amendments do not require the Examiner to conduct an additional search inasmuch as the amended claims define subject matter encompassed in the previous claims.

The Office Action includes rejections under Sections 103 and 112, which are discussed below.

Discussion of Rejections Under Section 112

Applicants disagree respectfully with the rejection of the claims as being based on a non-enabling disclosure. As discussed in detail in applicants' Reply dated May 7, 2002, it is believed that one of ordinary skill in the art would have no difficulty in making and using the full scope of the claimed invention. Nevertheless, in an effort to advance prosecution of the present application, independent Claim 25 has been amended to specify that the involved kappa opiate agonist compounds are arylacetamide compounds.[1] To the extent that the Examiner maintains that the rejection is applicable to the claims as amended herein, this rejection is traversed.

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1 This amendment is supported in the application, for example, at page 12, lines 2 to 3.

In this regard, it is submitted respectfully that the present application contains teachings that would enable a skilled artisan to practice the full scope of the methods defined in the pending claims, as amended herein. In this regard, the present application provides an extensive discussion of kappa opiate agonist compounds which are encompassed by the present claims and which are arylacetamides, as exemplified by the compounds of generic Formulas I, II, III and IV. *See* page 8, line 1 to page 134, line 14. Exemplary methods for making the disclosed arylacetamide compounds are taught in the present application (see page 12, line 13 to page 16; page 20, line 3 to page 23; page 25, lines 1 to 5; and page 27), and the working examples at pages 30 to 92 describe the preparation of numerous exemplary arylacetamides.

With respect to methods of use, the present application contains extensive teachings regarding, *inter alia*, the prevention or treatment of itch employing compounds as described in the present application. *See, e.g.*, page 112, line 3 to page 113, line 14. Teachings regarding formulations containing the present compounds are set forth at page 113, line 15 to page 121, line 4. Further teachings are provided regarding formulations in the form of lotions (page 121, line 5 to page 124, line 3), creams (page 121, lines 5 to 14), solutions and suspensions (page 124, line 15 to page 126, line 4), gels (page 126, lines 5 to 14), and solids (page 126, lines 15 to 30). Information regarding optional additional ingredients, combinations and kits, articles of manufacture, methods of treatment, and exemplary formulations are set forth at page 126, line 31 to page 134, line 14. It is submitted respectfully that the extensive teachings in the application, as exemplified above, would enable a skilled artisan to make and use the full scope of the claimed invention.

Applicants disagree respectfully with the rejection based on the term "substantially". As discussed in detail in applicants' May 7, 2002 Reply, it is believed that, when read in conjunction with the descriptive portion of the present application, a person of ordinary skill in the art would have no difficulty in understanding the meaning of this term. Nevertheless, to facilitate prosecution of the application, independent Claim 25 has been amended by deleting the term "substantially".

In view of the above amendments and remarks, reconsideration and withdrawal of the rejections under Section 112 are requested respectfully.

Discussion of the Rejections for Obviousness-type Double Patenting

Claims 25 and 27 to 32 have been rejected for obviousness-type double patenting in view of claims in Kruse et al., U.S. Patent No. 5,763,445, Kruse et al., U.S. Patent No. 5,981,513,[2] Kruse et al., U.S. Patent No. 6,028,063, and Kruse et al., U.S. Patent No. 6,180,623. To address these rejections, applicants submit herewith four Terminal Disclaimer documents and a Statement under 37 CFR 3.73(b). The Disclaimers are directed to disclaiming the portion of a patent granted on the present application which would extend beyond the terms of the patents cited in the obviousness-type double patenting rejections.

In view of the enclosed Terminal Disclaimers, reconsideration and withdrawal of the rejections for obviousness-type double patenting are requested respectfully.

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2 Applicants note that the patent cited in the Examiner's obviousness-type double patenting rejection, *i.e.*, U.S. Patent No. 5,598,513, is directed to "Color Recording Apparatus and Process Therefore", and is not owned by the assignee of the present application. It is applicants' understanding that the patent which was intended to be cited in connection with the obviousness-type double patenting rejection is the patent identified above, *i.e* U.S. Patent No. 5,981,513.

Discussion of the Art Rejection

Claims 25 and 27 to 32 have been rejected under 35 U.S.C. § 103 as being unpatentable over Dooley et al., U.S. Patent No. 5,610,271 ("Dooley") in view of of Lawhorn et al., "Epidural morphine with butorphanol for postoperative analgesia after cesarean delivery", *Anesthesia and Analgesia*, Vol. 72(1), pp. 53-57 (Jan. 1991) ("Lawhorn"). It is basically asserted in the Office Action that applicants' invention would have been *prima facie* obvious based on the combined teachings of the cited documents.

Applicants respectfully disagree with this rejection, and submit respectfully that the claims, as submitted to the Patent Office in applicants' Reply of May 7, 2002, define over these documents, alone or in any proper combination. Moreover, it is respectfully submitted that Claim 25, as amended herein to address the rejection under Section 112, first paragraph, further defines over these documents.

In this regard, as correctly acknowledged by the Examiner in paragraphs 7 and 8 of the Office Action, Dooley's teachings are limited to opioid peptides and their use in *in vitro* and *in vivo* methods. Dooley fails completely to disclose or suggest methods involving the use of kappa opiate receptor agonists which are not peptides, as described and claimed in the present application.

Lawhorn is directed to a study on the combined administration of morphine and butorphanol to patients undergoing epidural anesthesia for cesarean delivery. *See* abstract. Independent Claim 25 distinguishes over Lawhorn in that butorphanol, whose chemical name is N-cyclobutylmethyl-3,14-dihydroxymorphinan, is not an arylacetamide. There is no disclosure or suggestion in Lawhorn of arylacetamide compounds as defined in Claim 25, as

amended herein. Accordingly, it is submitted respectfully that Lawhorn fails to cure the deficiencies of Dooley, as applied against the present claims.

In view of the foregoing discussion, reconsideration and withdrawal of the Section 103 rejection are requested respectfully.

Conclusion

Applicants believe that the foregoing constitutes a complete and full response to the Office Action of record. Accordingly, an early and favorable reconsideration of the rejections and an allowance of all of pending Claims 15 and 27 to 32 are requested respectfully.

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

25. (Twice amended) A method of treating or preventing pruritus in a mammal in need of such prevention or treatment, said method comprising administering to said mammal an arylacetamide non-peptide kappa opiate receptor agonist, or a pharmaceutically acceptable salt thereof, that is ~~substantially~~ devoid of central nervous system effects, in a pharmaceutically acceptable carrier.